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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,574	10/03/2000	Shuwei Yang	0942.4500004/RWE/BJD	1982

26111 7590 04/08/2005

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WASHINGTON, DC 20005

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,574

Applicant(s)

YANG ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/2005 has been entered.

Applicants request to enter and consider the amendment and reply previously filed on 11/23/2004 is acknowledged.

Applicants amendment of claims 1 and 2 and the cancellation of claims 4-5, 41-46, 70, 76 and 78-82 in the paper of, 1/21/2005 (11/23/2004), is acknowledged.

Claims 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 are still at issue and are present for examination.

Applicants' arguments filed on 1/21/2005 (11/23/2004), have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office actions of 7/28/2004, 4/23/2002, 4/29/2003 and 12/4/2003 as it applied to the previous claims. In response to this rejection, applicants have amended the claims and continue to traverse this rejection as it applies to the newly amended claims.

The newly amended claims are directed to all possible *Thermotoga neopolitana* DNA polymerases which have been modified or mutated at a position corresponding to Arg 722, Lys 726 or both Arg 722 and Lys 726 of a *Thermotoga neopolitana* polymerase and kits comprising said modified polymerases.

Applicants have amended the above rejected claims such that they are no longer drawn to any Pol I type DNA polymerase, rather the claims are directed to mutant *Tne* DNA polymerases.

Applicants amendment and argument is fully acknowledged, however, the claims continue to be rejected under this statute for the reasons previously made of record and stated below.

There is no disclosure of any particular structure to function/activity relationship for the claimed genus of mutant *Thermatoga neapolitana* DNA polymerases, given that.

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Thermatoga neapolitana has a number of polymerases in addition to a Pol I type DNA polymerase. Given the lack of species representative of the claimed genus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Claims 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 are further rejected under this statute because the reference in claims 1 and 2, that the mutation at Lys 726 in the claimed double mutants, may be a substitution with an amino acid selected from the group consisting of "...Leu, **Lys**, Met ..." is not supported by the specification at the time of filing and is thus considered new matter. Applicants attention is directed to the recited substitution of Lys726 with Lys.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6-9, 14, 17, 20, 37-40, 69 and 71-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Francois et al. (Chatterjee U.S. Patent No. 5,948,614, September 1999, See IDS submitted 12/17/2003, Ref ACS).

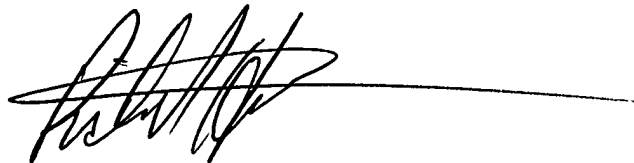
Chatterjee teach a Thermotoga (Tne and Tma) DNA polymerases and mutants thereof. Chatterjee specifically teach a Thermotoga DNA polymerase mutant in which Arg 722 is substituted with Asp, Glu, Ala, Asn, Lys and His. Chatterjee also teach a mutant Tne DNA polymerase in which Lys 726 is substituted with Tyr, Arg, His and Asp thus anticipating claims 1-7. While Chatterjee does not specifically teach that the taught modifications increase or enhance fidelity, or reduce or eliminate misincorporation of nucleotides, these are considered to be characteristics inherent to the taught DNA polymerase mutants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', followed by a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
3/30/2005